UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,611	03/29/2004	Atsushi Suzuki	251067US0CONT	9751

22850 7590 09/14/2004

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,611	SUZUKI ET AL.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/161,739.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/29/04 & 6/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 4-19 are pending.

2. Claims 4-19 are rejected.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

4. The information disclosure statement of March 29, 2004 and June 28, 2004 have been reviewed and considered, see enclosed copies of PTO FORM 1449.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 4-6, 9, and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cheng, J. T. et al. of abstract of XP-002219274. Cheng, J. T. et al. teach of treating hypertension with the administration of chlorogenic acid and other caffeoylquinic acids, namely methyl chlorogenate, which are embraced by the compounds of formula (I), (see abstract).

7. Claim 4 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Okawa et al. of EP 1,172,112 A2. Okawa et al. teach of treating hypertension with the administration of extract of coffee beans, which preferably contains chlorogenic acid, which are embraced by the compounds of formula (I), (see page 2, paragraphs 2 and 14).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 4-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng, J. T. et al. of abstract of XP-002219274. Cheng, J. T. et al. teach of treating hypertension with the administration of chlorogenic acid and other caffeoylquinic acids, namely methyl chlorogenate, which are embraced by the compounds of formula (I), (see abstract). Cheng, J. T. et al. are silent to pharmaceutical dosages and modes of administration and amide-containing derivatives of chlorogenic acid. However, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition, the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds of Cheng, J. T. et al.

Obviousness-type Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 4-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-9 and 11-31 of copending Application No. 09/944,079. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and the copending Application No. 09/944,079 teach of treating hypertension with a compound that is a chlorogenic acid, ester or salt thereof. Moreover, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition, the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds. In addition, both applicant and the copending Application No. 09/944,079 recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

14. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 4-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-19 and 23-26 of copending Application No. 10/192,075. Although the conflicting claims are not

identical, they are not patentably distinct from each other because both the instant invention and the copending Application No. 10/192,075 teach of treating hypertension with a compound that is a chlorogenic acid, ester or salt thereof. Moreover, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition, the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds. In addition, both applicant and the copending Application No. 10/192,075 recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

16. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 4-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 6 of copending Application No. 10/626,708. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and the copending Application No. 10/626,708 teach of treating hypertension with a compound that is a chlorogenic acid, ester or salt thereof. Moreover, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition,

the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds. In addition, both applicant and the copending Application No. 10/626,708 recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

18. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 4-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-17 of U.S. Patent No. 6,458,392. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and U.S. Patent No. 6,458,392 teach of treating hypertension with a compound that is a chlorogenic acid, ester or salt thereof. Moreover, it is well within the level of the skilled artisan to determine therapeutic dosages, modes and methods of administration in order to optimize the efficacy of a pharmaceutical agent. In addition, the skilled artisan would have been motivated to determine and select pharmaceutically acceptable acyl, ester, and amide moieties and derivatives with the known chlorogenic compounds. In addition, both applicant and U.S. Patent No. 6,458,392 recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates

additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (703) 872-9306.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should

you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
September 10, 2004